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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,790	10/19/2001	Todd J. Mortier	7528.0003-01	6743

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EXAMINER

WILLSE, DAVID H

ART UNIT	PAPER NUMBER
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3738

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DATE MAILED: 01/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/981,790

Applicant(s)

MORTIER ET AL.

Examiner

Dave Willse

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-30 and 45-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-30 and 45-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 19. 6) ☐ Other: _____

Art Unit: 3738

Claim 65 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 65, lines 1-2, "the geometry of the *heart* structure" (emphasis added) lacks a proper antecedent basis.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 58, 65, and 68 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Reimold et al., WO 95/16407. Figures 1 and 8 illustrate a device **12** positioned with respect to a heart **2** such that a portion of the device **12** contacts and alters a geometry of aortic structure **4**

Art Unit: 3738

(via elements **46**, **50**, and/or **18**, for example) so as to alter a portion of an annulus of an *in situ* aortic valve and to draw together leaflets of said valve (Figure 3; page 5, lines 10-17; page 6, lines 4-20).

Claims 18, 22, 23, 26-30, 45, 46, 48-59, 61-73, 75, 76, and 78 are rejected under 35 U.S.C. 102(e) as being anticipated by Fasol et al., US 2003/0105519 A1, which discloses a method of using at least one elongate member **11** (paragraph **0036**, lines 2-3) having an anchor assembly in the form of sutures **16** and **17** and needles (paragraph **0037**, lines 1-3). Regarding claim 18 and others, anchoring the ends of the elongate member **11** inherently draws together leaflets of the *in situ* valve, as seen from paragraphs **0005** and **0010**, for example. The further limitation of claim 26 and others is deemed to be inherent in the Fasol et al. procedure in view of the last sentence of paragraph **0004**. Regarding claim 70, the *in situ* valve of lines 2-3 is viewed as the aortic valve, for example, and the *in situ* valve of lines 4 and 5 is interpreted as the mitral valve.

Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fasol et al., US 2003/0105519 A1. Supplementing the Fasol et al. procedure with an annuloplasty ring, well known in the art, would have been obvious for patients in which re-shaping and/or supporting the valve annulus is indicated, with further motivation having been provided at paragraph **0005**, first two sentences, because both devices are alternatives to heart valve replacements.

Claims 70-73 and 75-78 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kusuhara, US 5,360,444: Figures 4-10. It is again noted that the *in situ* valve on lines 2-3 of present claim 70 is not necessarily the *in situ* valve set forth on lines 4 and 5 of said claim.

Regarding claim 78, because the supporter can be used with a mitral valve **2**, the drawing

Art Unit: 3738


together of the leaflets and the alteration of heart geometry inherently shifts the position of at least one papillary muscle.

Claims 74 and 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kusuhara, US 5,360,444. Regarding claims 74 and 79, portions of the sutures inherently traverse the heart wall; alternatively, mechanical anchors and the like were well known in the art and would have been an obvious variant in order to simplify the surgical procedure.

Claims 18-30 and 45-79 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Melvin, US 5,957,977. Regarding claim 18 and others, the drawing together of leaflets of the *in situ* valve is deemed to be inherent from column 2, lines 51-54, and from the structure and intended use of the device.

The Applicant's remarks have been reviewed and are adequately addressed above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is (703) 308-2903. The examiner can normally be reached Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Dave Willse
Primary Examiner
Art Unit 3738